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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/229,226 01/12/99 LIU

J GTRC-1957

EXAMINER

QM12/0503

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ART UNIT PAPER NUMBER

3737
DATE MAILED:

05/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/229,226

Applicant(s)

LIU ET AL.

Examiner

Ruth S Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The frequency range set forth in claim 14, and the measured frequencies set forth in claim 20 lacks antecedent basis in the specification.

The abstract of the disclosure is objected to because it includes legal phraseology such as the term "means". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

Claims 9,17,19-22,26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9,17 are vague and indefinite in that it is unclear as to what further step in the method has been set forth. It appears that such limitations are inherent results of the method. Claims 19,20 are vague and indefinite in that on lines 1-2 "the acoustic energy or pressure" lacks antecedent basis. In claim 21, "the acoustic spectrum" lacks antecedent basis. The use of the term "such as" renders claim 22 vague and indefinite. Claim 26 is vague and indefinite in that it is unclear as to what structure of the device has been defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,3-5,8-12,14,15,17,18,23,25,26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden. The claims are directly readable on Ogden which

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discloses the use of ultrasound energy to alter transport of agents into the body. The frequency and treatment time can be changed. A feedback loop is used to monitor drug delivery amounts and temperature and the treatment is affected by such measurements. The agents and enhancers set forth in the claims are disclosed in column 5.

Claims 1-3,5,7,14,15,18,23,25,26 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al. The claims are directly readable on Tachibana et al which disclose the use of ultrasound to alter cell viability. The ultrasound is administered for a predetermined time period after which it is terminated. The intensity was varied over time and the ultrasound was used to kill cells. The ultrasound was applied at a frequency of 270 KHz and used with agent such as Photofrin II. Figure 1 shows the device used to carry out the method.

Claims 27-28,30,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Eppstein et al. The claims are directly readable on Eppstein et al which disclose the use of ultrasound energy to alter transport of agents into the body. The frequency can be changed such that the energy is directed to a deeper part of the tissue. Therefore, the energy is administered at the skin by a transducer placed thereon and the energy alters transport and cell viability at a site distant from the layer of skin on which the transducer is placed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,8-18,23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bommannan. Bommannan et al disclose administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The energy is administered for a time period which can be selected based upon the drug administered, and the disease or injury treated (see column 7, lines 6-10). It would have been obvious to one skilled in the art to have monitored the treatment time and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient. The agent passed through the membrane can be peptides or proteins and in the form of an emulsion. Bommannan et al further disclose that the method can be used to sample and evaluate biological fluids in the body (see column 4, lines 55-59). With regard to claim 9, it appears that such is an inherent function of the method. With regard to claim 13, it appears that the method of Bommannan et al would be applicable to any type of biological membrane. With regard to claim 14, Bommannan et al disclose a frequency above about 10MHz. In the absence of any showing of criticality, it would have been obvious to one skilled in the art to have used to frequency set forth by Bommannan et al in that such is a difference in degree rather than kind from the frequency set forth in the claim. It should be noted that applicant discloses frequencies in the range of up to 100 MHz can be used. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 17, the step

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is an inherent result of the method. With regard to claims 23,24, the total exposure time and device location can be changed depending upon the procedure being performed.

Claims 1-5,8-18,23-26,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein et al. Eppstein et al disclose administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The frequency and/or intensity can be selected based upon the drug administered, and the disease or injury treated. It would have been obvious to one skilled in the art to have monitored the treatment time and intensity/frequency used and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient. With respect to claim 3, the agent passed through the membrane would have been an obvious selection based upon the intended treatment, and in the form of an emulsion or liposome as is well known. With regard to claim 9, it appears that such is an inherent function of the method. With regard to claims 13,29, it appears that the method of Eppstein et al would be applicable to any type of biological membrane and to any type of cell. With regard to claim 14, Eppstein et al disclose a frequency in the range of .1-100MHz. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 17, the step is an inherent result of the method. With regard to claims 23,24, the frequency and device location can be changed depending upon the procedure being performed.

Claims 2,13,16,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden. Ogden discloses administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The frequency and/or intensity can be selected based upon the drug administered, and the disease or injury treated. It would have been obvious to one skilled in the art to have monitored the treatment time and intensity/frequency used and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient. With

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regard to claim 13, it appears that the method of Ogden would be applicable to any type of biological membrane and to any type of cell. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 24, the frequency and device location can be changed depending upon the procedure being performed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is 308-3063. The examiner can normally be reached on M-F 5:30AM -2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0858.



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS
May 3, 2001